

**The Department of Health and Human Services  
Meeting of the  
Secretary's Advisory Committee on Human Research Protections (SACHRP)**

**Monday, October 4 and Tuesday, October 5, 2004  
The Radisson Hotel Old Town Alexandria  
901 North Fairfax Street  
Alexandria, VA**

**DRAFT AGENDA**

**Monday, October 4**

8:30 am – 8:35 am	Welcome: Opening Remarks <b>Ernest Prentice, Ph.D.</b> <b>Chairman, SACHRP</b>
8:35 am – 8:45 am	Report on Issues <b>Bernard Schwetz, D.V.M., Ph.D.</b> <b>Director, OHRP</b>
8:45 am – 9:00 am	Overview of Charges to Subcommittees Approval of Minutes from July 26, 27 meeting <b>Ernest Prentice, Ph.D.</b> <b>Chairman, SACHRP</b>
9:00 am – 9:30 am	Public Comment
9:30 am – 10:30 am	Report of Subcommittee on Research Involving Children <b>Dr. Celia Fisher, Co-Chair</b> <b>Susan Kornetsky, Co-Chair</b>
10:30 am – 10:45 am	Break
10:45 am – 12:00 noon	Report of Subcommittee on Research Involving Children
12:00 noon – 1:00 pm	LUNCH
1:00 pm – 3:00 pm	Report of Subpart C Subcommittee on Research Involving Prisoners <b>Mark Barnes, J.D., LL.M.</b> <b>Nancy Dubler</b>

3:00 pm – 3:15 pm

Break

3:15 pm – 3:45 pm

Discussion of committee business

3:45 pm – 4:15 pm

Public Comment

4:15 pm – 5:00 pm

Summary of day's activities/committee business

5:00 pm

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**Tuesday, October 5**

8:30 am – 8:45 am	<b>Additional business</b> <b>Ernest Prentice, Ph.D.</b> <b>Chairman, SACHRP</b>
8:45 am – 10:45 am	<b>Subpart A Issues panel</b> <b>Ada Sue Selwitz, M.A.</b> Director, Office of Research Integrity University of Kentucky <b>David G. Forster, J.D., M.A.</b> Director, Regulatory Affairs Western IRB <b>Daniel K. Nelson, M.S., C.I.P.</b> Director, Human Research Studies University of North Carolina, Chapel Hill <b>Steven Peckman</b> Associate Director, Human Subjects Research Office for the Protection of Human Research Subjects University of California, Los Angeles
10:45 am – 11:00 am	Break
11:00 am – 11:30 pm	Public Comment
11:30 pm – 12:30 pm	LUNCH
12:30 pm – 2:30 pm	<b>Definition of Research vs. Non-Research Issues panel</b> <b>Michael Carome, M.D.</b> Associate Director for Regulatory Affairs OHRP <b>James Hodge, Jr., J.D., LL.M.</b>

Executive Director, Center for Law  
& the Public's Health  
Johns Hopkins University  
**Mary Ann Baily, Ph.D.**  
Associate for Ethics and Health Policy  
The Hastings Center  
**Margaret E. (Peggy) O'Kane, M.H.D.**  
President  
NCQA (National Committee for Quality Assurance)

2:30 pm – 2:45 pm

Break

2:45 pm – 4:45 pm

**Models of IRB Review**  
**Michael Carome, M.D.**  
Associate Director for Regulatory Affairs  
OHRP  
**David LePay, M.D., Ph.D.**  
Senior Advisor on Clinical Science  
Office of Science and Health Coordination  
Office of the Commissioner  
FDA  
**Susan Kornetsky**  
Director, Clinical Research Compliance  
Children's Hospital  
Boston, MA  
**Robert Levine, M.D.**  
Yale University Medical School  
**David Forster, J.D., M.A.**  
Director, Regulatory Affairs  
Western IRB  
**Lowell Schnipper, MD**  
Beth Israel Deaconess Medical Center  
Boston, MA

4:45 pm – 5:00 pm

Discussion of Committee business/wrapup

5:00 pm

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